



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 20 2004

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

WARNING LETTER

VIA FEDERAL EXPRESS

Gilles Pierson
President and CEO
Satelec Acteon Group
Z.I. du Phare, BP 216
17 Avenue Gustave Eiffel
33708 Merignac
France

Dear Mr. Pierson:

During an inspection of your establishment located in Merignac, France, on September 22-25, 2003, our investigator determined that your establishment manufactures the Servotome electrosurgical unit; the Team-Up™ Dental Electronic Anesthesia System; the Suprasson P5 Booster, the Propy PU2000, PU2000 S, PMAX, and PMAX LUX ultrasonic scalers; the ACTA and ACTA OEM Module ultraviolet light-curing units; and the SUNI MAX air-powered handpiece. These products are medical devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated under section 501(h) of the Act, in that the methods used in, or the facilities or controls used for their manufacture, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements for medical devices which are set forth in the Quality System regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. Significant deviations include, but are not limited to, the following:

1. 21 CFR 820.75(a)

Failure to fully document process validation activities and results, as required by 21 CFR 820.75(a). For example, you did not establish a validation plan (protocol) for the sterilization validation activities conducted by the contract sterilizer in 2000 for the [REDACTED].

Page 2 - Mr. Pierson

Your October 3, 2003, response is not adequate. You must provide English translations of the sterilization validation protocols to be used by [REDACTED] for the [REDACTED]. These sterilization validation protocols should include but not be limited to those for: the physical qualification of the sterilization equipment; the sub-lethal cycle, and the bacteriologic qualification.

2. 21 CFR 820.75(c)

Failure to document the review and evaluation of a process and the revalidation of a process conducted in response to changes or process deviations, as required by 21 CFR 820.75(c). For example, there is no documentation for a current change from the process parameters set at validation. Pressure values have been changes and are different from those established at validation.

Your October 3, 2003, response is partially adequate. You must provide an English translation of the contract with [REDACTED] that prohibits any change from the process parameters without Satelec's permission.

3. 21 CFR 820.100(b)

Failure to document corrective and preventive action activities including the actions needed to correct or prevent recurrence of nonconforming product and other quality problems, as required by 21 CFR 820.100(b). For example, there is incomplete documentation of corrective actions necessary for nonconformances noted during quality audits, no documentation of corrective action for administrative complaints and incomplete documentation of corrective action necessary for two technical complaints.

Your October 3, 2003, response may be adequate. You should provide English translations of the response forms for audit discrepancies and administrative complaints. You should also provide English translations of the correction actions forms and the customer complaint reply forms (Annex B and Annex C of your October 3, 2003, response).

4. 21 CFR 820.20 (b)(1)

Failure to assign the appropriate responsibility and authority to employees who manage, perform, and assess work affecting quality and provide them with the independence and authority to accomplish their work, as required by 21 CFR 820.20 (b)(1). For example, Quality Assurance (QA) is not responsible for inspection/testing of materials, components, in-process units or finished devices. QA does not review production records, monitor quality defects and has no responsibility for the evaluation or release of devices manufactured at this firm. Production employees perform manufacturing, assembly and final product release.

Your October 3, 2003, response may be adequate. It will be confirmed during the next inspection.

5. 21 CFR 820.22

Failure to conduct quality audits at sufficient regular intervals, as prescribed by internal procedures to verify that the quality system is effective in fulfilling your quality system objectives, as required by 21 CFR 820.22. For example, quality audits scheduled to be conducted at 12 month intervals have not been done. Audit of the Preventative Maintenance area was last conducted April 2001, and audits for the tip manufacturing and instruction manuals were last performed May 2001. Additionally, the Corrective/Preventative Action System and Design Controls were audited at 12 months intervals.

Your October 3, 2003, response may be adequate. It will be confirmed during the next inspection.

6. 21 CFR 803.18(b)(1)(i)

Failure to establish and maintain Medical Device Reporting (MDR) event files to contain or reference all adverse event information in the possession of the reporting entity, including documentation of the deliberations and decision making process used to determine if an event was or was not reportable, as required by 21 CFR 803.18(b)(1)(i). For example, your firm has not determined if a reported event of possible patient injury after use of the Mint Powder, is

Page 4 - Mr. Pierson

a reportable event. The complaint was received May 5, 2003, and to date no investigation has been made to determine the extent of patient injury and/or medical intervention. The complaint is outstanding and no assessment has been made as whether an MDR should be filed.

Your October 3, 2003, response is not adequate. Your firm has still not evaluated complaint [REDACTED] for MDR reportability. This complaint concerned a patient experiencing mouth swelling and discoloration during a procedure using the Prophy mint powder. Additionally you need to provide an English translation of the revised Customer Complaint Procedure [REDACTED] which includes the revised wording concerning 21 CFR 803. You also need to provide an English translation of the decision tree [REDACTED] (Annex D of your October 3, 2003, response).

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in action without further notice, which may include detaining your devices without physical examination upon entry into the U.S. until corrections are completed. Section 801(a) of the Act, U.S.C. 381(a)). Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

We acknowledge the receipt of your October 3, 2003, letter in response to the FDA 483 observations issued to you at the conclusion of the inspection.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will

Page 5 - Mr. Pierson

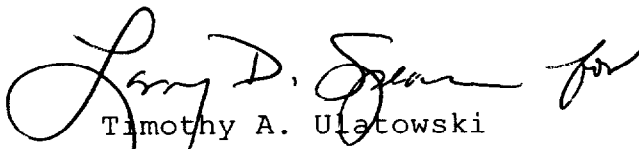
not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Please direct your response to:

Mr. Ronald L. Swann
Chief
Dental, Ear, Nose Throat, and
Ophthalmic Devices Branch (HFZ-331)
Division of Enforcement A
Office of Compliance
Center for Devices and Radiological Health
U.S. Food and Drug Administration
2098 Gaither Road
Rockville, Maryland 20850
U.S.A.

If you have questions about the content of this letter, please contact Mr. Swann at the above letterhead address or at 301-594-4613 or by fax at 301-594-4638.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Timothy A. Ulatowski", followed by a small flourish or mark.

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health